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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,969	01/15/2002	Yousuke Moriuchi	026575-065	2991
7590	04/30/2004		EXAMINER	
Platon N. Mandros BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			PANTUCK, BRADFORD C	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 04/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/044,969	MORIUCHI ET AL.	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on April 7, 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 8-15 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 January 2002 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/8/02, 8/28/03</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>IDS 01/13/04</u> |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species I in Paper No. 03-26-2004 is acknowledged. The traversal is on the ground(s) that both inventions can be searched without a tremendous burden. This is not found persuasive because the stent structure classification subclass is an extremely crowded area, in which a seemingly small structural difference differentiates over the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 8-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 03-26-2004.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. For example, Applicant could say that the title is: "Stent with waved connecting ridges."

Claim Objections

4. Claim 1 is objected to because of the following informalities: In line 16 "waved element" should be "waved elements". Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, and 4-7 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,183,506 B1 to Penn et al. Regarding Claim 1, Penn discloses a tubular stent, which is capable of expansion [Column 1, line 6]. The stent has a plurality of annular expanding members, each formed of a wave element [Fig. 10]. Penn also discloses a plurality of waved connecting members (936 or 971) connecting ridges and/or bottoms. There is no phase difference between the waves of adjacent annular expanding members. Furthermore, one of the waves of each waved connecting member (971) has a larger amplitude than the other wave, as is evident from Fig. 10 and described in Column 10, lines 50-52.

6. Regarding Claim 2, the ridges of adjacent annular expanding members are connected by waved connecting members and the bottoms of adjacent annular expanding members are connected by waved connecting members. In other words, waved connecting member (971) *alone* connects either a ridge to a ridge *or* a bottom to a bottom—*depending on one's perspective*.

7. Regarding Claim 4, Penn discloses a stent with waved connecting members having a thickness of anywhere between 0.00381 mm and 0.1143 mm [Column 11,

line 66 to Column 12 line 10]. Although the “polygon” that Penn refers to is in seemingly direct reference to the waved connecting members/annular expanding members of Fig. 1A, it can be assumed that these *same components of Fig. 10* will have a similar range of thickness. Furthermore, because the Patent and Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed subject matter is not anticipated or unobvious, the examiner properly shifts the burden to applicants to show *unanticipated* or unobvious differences exist, Ex parte Phillips, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

8. Regarding Claim 5, Penn discloses a largest wave of a waved connecting member (971) that is larger than the width of the ridge or bottom of the waved element, as can be seen in Attachment #1. Applicant does not specify which aspect of the largest wave member is larger than the width of the ridge. Penn discloses a largest wave member, in which one dimension (length) is larger than the width of the ridge, as shown in Attachment #1.
9. Regarding Claim 6, the length of the waved connecting member is 1.3 times as much as the straight distance between ridges of the waved elements of adjacent annular expanding members, as measured in Fig. 10 using a string. Further, “strut” 970 (equivalent to Applicant’s “waved connecting member”) is said to be up to 35% longer than the distance between the two ridges of the adjacent annular expanding members [Column 5, lines 57-62].
10. Regarding Claim 7, when the drawings of Applicant are superimposed on the drawings of Penn, the clearance width between adjacent annular expanding members

is identical. Although this does not prove with absolute certainty that this distance is necessarily between 0.4 mm and 0.8 mm it does prove that the proportions of Penn are the same as the proportions of Applicant's invention. Furthermore, *because Penn's invention is intended for use in the same part of the body as Applicant's invention (arteries/veins) this strongly suggests that the two stents would be largely the same size and thus have the same size in addition to the same proportions.*

Finally, because the Patent and Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed subject matter is not anticipated or unobvious, the examiner properly shifts the burden to applicants to show *unanticipated* or unobvious differences exist, Ex parte Phillips, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Publication No. WO 99/36002 to Vardi et al. Regarding Claim 1, Figure 10 shows an expanding stent with waved connecting members (114) having waves with varying amplitudes and the other features claimed by the Applicant.
12. Regarding Claim 3, upon visual inspection of the proportions shown in Figure 10, the width of each waved connecting member (114) is less than half the thickness of the waved elements of the annular expanding members. Further, because the Patent and Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed subject matter is not anticipated or unobvious, the

examiner properly shifts the burden to applicants to show *unanticipated* or unobvious differences exist, Ex parte Phillips, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on (703) 308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Milano
Supervisory Patent Examiner
Art Unit 3731

BCP
BCP
April 26, 2004